

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

**STATE OF MINNESOTA, by its Attorney
General Keith Ellison,**

Plaintiff,

v.

SANOFI-AVENTIS U.S. LLC, et al.;

Defendants.

Case No. 2:18-cv-14999 (BRM)(AME)

**SUPPLEMENTAL CONFIDENTIALITY
ORDER AND HIPAA QUALIFIED
PROTECTIVE ORDER**

1. PURPOSES AND LIMITATIONS

Disclosure and discovery activity in this Action are likely to involve production of confidential, proprietary, or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this Action may be warranted. Accordingly, the Parties in this Action stipulated to and entered a Confidentiality Order (ECF No. 90), which applies to this Action and *In re Insulin Pricing Litigation*, 17-cv-699 (BRM)(ESK). The Parties to this Action hereby further stipulate and petition the court to enter the following Supplemental Confidentiality Order and HIPAA Qualified Protective Order (“Supplemental Order”), at the request of certain Minnesota Agencies and to facilitate the production of information and/or items from those Minnesota Agencies. The Parties acknowledge that this Supplemental Order is intended to address the protections applicable to certain materials that may be produced in this Action, and that this Supplemental Order shall not replace or supersede the terms in the Confidentiality Order unless inconsistent with a procedure or protocol in this Supplemental Order. The Parties further acknowledge that this Supplemental Order does not confer blanket protections on all disclosures or responses to discovery and that the protection it affords from public disclosure and use extends only to the limited information or items that are

entitled to confidential treatment under the applicable legal principles. The Parties further acknowledge, as set forth in Section 11.3 of the Confidentiality Order, that the Confidentiality Order does not entitle them to file confidential information under seal; Local Civil Rule 5.3(c) sets forth the procedures that must be followed and the standards that will be applied when a party seeks permission from the court to file material under seal.

In accordance with the Parties' stipulation and the requirements of the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), specifically, 45 C.F.R. § 164.512(e)(1)(ii)(B) and § 164.512(e)(1)(v), the Court hereby enters this Supplemental Confidentiality Order and HIPAA Qualified Protective Order. In addition to facilitating compliance with the foregoing federal laws and regulations, this Supplemental Order is entered to facilitate compliance with applicable state laws and regulations governing patient privacy and protecting healthcare information.

2. DEFINITIONS

2.1 **Action:** The word "Action" is defined as the above-entitled action.

2.2 **"CONFIDENTIAL" Information or Items:** information (regardless of how it is generated, stored, or maintained) or tangible things that contain private or non-public information, including but not limited to:

(a) trade secrets, competitively sensitive technical, marketing, financial, sales or other confidential business information, including trade secret information as defined by Minnesota Statutes section 13.37, subdivision 1(b);

(b) information classified as "private data on individuals," "not public," or "confidential data on individuals" by the Minnesota Government Data Practices Act, Minnesota Statutes chapter 13;

(c) private or confidential personal information;

(d) information received in confidence from third parties; or

(e) information that the producing party otherwise believes in good faith to be entitled to protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure and Local Civil Rule 5.3.

2.3 **Covered Entities:** shall have the same scope and definition as set forth in 45 C.F.R. § 160.103.

2.4 **De-Identified Information:** shall have the same scope and definition as set forth in 45 C.F.R. § 164.514(a).

2.5 **Individual:** shall have the same scope and definition as set forth in 45 C.F.R. § 160.103.

2.6 **Minnesota Agency:** shall mean only the following entities

(a) the Minnesota Board of Pharmacy;

(b) the Minnesota Department of Commerce;

(c) the Minnesota Department of Corrections;

(d) the Minnesota Department of Human Services;

(e) the Minnesota Department of Health;

(f) the Minnesota Department of Administration; and

(g) the Minnesota Department of Management and Budget.

2.7 **Protected Health Information or “PHI”:** shall have the same scope and definition as set forth in 45 C.F.R. § 160.103.

2.8 **Protected Personal Data:** any Disclosure or Discovery Material that a Party or Minnesota Agency believes in good faith requires additional protections, beyond those provided to information designated as “CONFIDENTIAL” pursuant to this

Supplemental Order, the Confidentiality Order, under applicable federal, state or foreign data protection laws or other privacy obligations. Examples of such data protection laws include but are not limited to the Gramm-Leach-Bliley Act, 15 U.S.C. § 6801; the Health Insurance Portability and Accountability Act and the regulations thereunder, 45 CFR Part 160 and Subparts A and E of Part 164 (HIPAA); the European Union's General Data Protection Regulation, Regulation (EU) 2016/679 (GDPR); and the Danish Act on Data Protection. Protected Personal Data includes Protected Health Information, as defined in 2.19. However, information designated as Protected Personal Data based on a foreign privacy requirement may be so designated only where the information in question is subject to that foreign privacy requirement.

- 2.9 **Search Term:** a word or a combination of words or phrases designed to capture potentially relevant information, which includes strings of words and phrases joined by proximity and Boolean connectors or other syntax.

3. SCOPE

- 3.1 This Supplemental Order shall apply to all discovery material produced by a Minnesota Agency through the use of Search Terms, or other means.
- 3.2 Nothing in this Supplemental Order shall be applicable to Disclosures or Discovery Material already produced by any Party prior to the effective date of this Supplemental Order.
- 3.3 This Supplemental Order does not entitle any Party to documents or information to which they would not otherwise be entitled under the Federal Rules of Civil Procedure, applicable discovery rules, and other pretrial orders. Nothing in this Supplemental Order shall preclude any Party or Minnesota Agency from asserting

any objection to the relevance, discoverability, admissibility, or privileged nature of the documents authorized to be disclosed by this Supplemental Order. The entry of this Supplemental Order does not prevent any Party or Minnesota Agency from seeking a further order pursuant to Federal Rule of Civil Procedure 26(c) or any applicable state procedural rule or provision governing the terms on which disclosure may be made.

- 3.4 The Parties and Minnesota Agencies may seek additional protection from the disclosure and use of any documents and information for which they believe this Supplemental Order does not provide adequate protection or with respect to documents and information that they believe are not subject to disclosure pursuant to applicable statutes, rules, regulations, or other applicable law.
- 3.5 This Supplemental Order does not control or limit the use of PHI that was received by means other than through the parties' discovery requests (for example, through consent of the Individual or through a public records request).
- 3.6 The Confidentiality Order (ECF No. 90) shall apply unless inconsistent with a procedure or protocol in this Supplemental Order.

4. ACCESS TO AND USE OF PROTECTED MATERIAL

- 4.1 **Treatment of Protected Personal Data.** Protected Personal Data that contains PHI produced by a Minnesota Agency is subject to the provisions of Section 11 (PRODUCTION AND USE OF PROTECTED HEALTH INFORMATION) of the Confidentiality Order (ECF No. 90) entered in *In re Insulin Pricing Litigation*, 17-cv-699(BRM)(ESK).

5. PRODUCTION AND USE OF PROTECTED HEALTH INFORMATION

- 5.1 All Minnesota Agencies who receive or have already received in the Action a discovery request for documents or information are hereby authorized to disclose PHI to the extent necessary to comply with such a discovery request. Minnesota Agencies may disclose PHI pursuant to this Supplemental Order to any Party in the Action or to any Party's attorney (including the agents and employees of the Parties and their attorneys) without violating the provisions of HIPAA. A Party producing documents of Minnesota Agencies that contain PHI shall first stamp each document containing PHI with the following stamp: "Protected Health Information Subject to HIPAA Qualified Protective Order."
- 5.2 Subject to the limitations of Section 7.4 of the Confidentiality Order (ECF No. 90), the Parties, Minnesota Agencies, and their attorneys (including the agents and employees of the Parties and their attorneys) are hereby authorized through discovery in this case to disclose, receive, subpoena, and transmit PHI. The Parties and Minnesota Agencies may not object to Search Terms designed to capture potentially relevant documents or information on the basis that the documents or information sought contain PHI protected by HIPAA.
- 5.3 Pursuant to 45 C.F.R. § 164.512(e)(1)(v)(A), the Parties and their attorneys shall be allowed to use or disclose PHI for this Action, and any appeals, settlement proceedings, enforcement, or monitoring that may result from this Action. The Parties and their attorneys may not use the PHI for any other purpose. Authorized uses include disclosure to the Court and support staff, Special Masters and their support staff, the Parties and the Parties' employees, their attorneys of record, the

attorneys' firms (*i.e.*, attorneys and support staff), the Parties' experts, consultants, mediators, court reporters, videographers, copy services, and e-discovery vendors.

5.4 If a Party wishes to file a document containing PHI with the Court, the Party must file the document under seal, following the procedures set forth in Local Civil Rule 5.3(c), and provide a copy of the unredacted version of the document to the other Parties.

5.5 Subject to Section 7.4 of the Confidentiality Order, any Party or Minnesota Agency may discuss PHI covered by this Supplemental Order at a deposition. The Party or Minnesota Agency must request that this portion of the testimony be marked as "Protected Health Information Subject to HIPAA Qualified Protective Order" on the record during the deposition or within a reasonable time following the conclusion of the deposition. Any Party must comply with the requirements of this Supplemental Order, including those in the preceding paragraph, before filing any deposition testimony containing PHI with the Court.

5.6 Subject to Section 7.4 of the Confidentiality Order, any Party may use documents containing PHI at trial, an evidentiary or other motion hearing, including but not limited to, introducing them into evidence and asking a witness about their contents. If a Party moves a document containing PHI into evidence and wants it to be a part of the record, the Court shall appropriately instruct the Clerk on how to handle such documents.

6. CONFIDENTIAL REBATE DATA

6.1 Nothing in this Supplemental Order shall be construed to permit or require disclosure of information identified as confidential under 42 U.S.C. § 1396r-8(b)(3)(D).

IT IS SO ORDERED.

Dated: October 29, 2021

s/Dennis M. Cavanaugh

Hon. Dennis M. Cavanaugh (Ret.),
Special Master

IT IS SO STIPULATED, THROUGH COUNSEL OF RECORD.

Dated: October 29, 2021

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EXHIBIT A

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**STATE OF MINNESOTA, *by its Attorney
General Keith Ellison,***

Plaintiff,

v.

SANOFI-AVENTIS U.S. LLC, et al.;

Defendants.

Case No. 2:18-cv-14999 (BRM)(AME)

**ACKNOWLEDGEMENT OF AND AGREEMENT TO BE BOUND BY THE
SUPPLEMENTAL CONFIDENTIALITY ORDER**

I, _____ state that:

My business address is _____

My present employer and job description are _____

My relationship to the parties to the Action is as follows: _____

I declare under penalty of perjury that I have read in its entirety and understand the Supplemental Confidentiality Order and HIPAA Qualified Protective Order issued by the United States District Court for the District of New Jersey on **[DATE]** in the action *State of Minnesota v.*

Sanofi-Aventis U.S. LLC, et al., Civil Action No. 2:18-cv-14999(BRM)(AME) (the “Supplemental Order”).

I agree to comply with and to be bound by all the terms of the Supplemental Order. I promise that I will not disclose in any manner any information or item that is subject to the Supplemental Order to any person or entity except in strict compliance with the provisions of the Supplemental Order. I understand and acknowledge that failure to so comply could expose me to sanctions and punishment. I further agree and attest to my understanding that my obligation to honor the confidentiality of such discovery material will continue even after the Action concludes. I understand that my execution of this Acknowledgement Of Agreement To Be Bound By the Supplemental Confidentiality Order, indicating my agreement to be bound by the Supplemental Order is a prerequisite to my review of any information designated as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” pursuant to this order.

I further agree to submit to the jurisdiction of the United States District Court for the District of New Jersey for the purpose of enforcing the terms of the Supplemental Order, even if such enforcement proceedings occur after termination of this action.

I understand that contempt sanctions may be entered for violation of this Supplemental Order and further agree to submit to the jurisdiction of this Court for the purposes of enforcement of the terms of this Supplemental Order.

DATED this _____ day of _____, _____.

(Signature)
(Typed or Printed Name)

CERTIFICATE OF SERVICE

I do hereby certify that a copy of the foregoing has been filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's electronic filing system.

This 29th day of October, 2021

/s/ Melissa A. Geist

Melissa A. Geist